General

Guideline Title

Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Aug. 62 p. (Technology appraisal guidance; no. 295).

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Everolimus, in combination with exemestane, is not recommended within its marketing authorisation for treating postmenopausal women with advanced human epidermal growth factor receptor 2 (HER2)-negative hormone-receptor-positive breast cancer that has recurred or progressed following treatment with a non-steroidal aromatase inhibitor (NSAI).

Women currently receiving everolimus for advanced breast cancer should be able to continue treatment until they and their clinician consider it appropriate to stop.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Advanced human epidermal growth factor receptor 2 (HER2)-negative hormone-receptor-positive breast cancer

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Endocrinology

Family Practice

Internal Medicine

Obstetrics and Gynecology

Oncology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To assess the clinical effectiveness and cost-effectiveness of everolimus in combination with exemestane for treating advanced human epidermal growth factor receptor 2 (HER2)-negative hormone-receptor-positive breast cancer after endocrine therapy

Target Population

Postmenopausal women with advanced human epidermal growth factor receptor 2 (HER2)-negative hormone-receptor-positive breast cancer that has recurred or progressed following a non-steroidal aromatase inhibitor (NSAI)

Interventions and Practices Considered

Everolimus in combination with exemestane (not recommended)

Major Outcomes Considered

- Clinical effectiveness
    - Progression-free survival/time to progression (PFS/TTP)
    - Overall survival (OS)
    - Overall response rate
    - Health-related quality of life (HRQoL)
    - Duration of response
    - Time to response
    - Clinical benefit rate
    - Adverse events
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the Liverpool Reviews and Implementation Group (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Searches

Systematic Review

The following databases were searched by the manufacturer, 8 to 9 March 2012:

- MEDLINE and MEDLINE In-Process (OvidSP)
- EMBASE (OvidSP)
- Science Citation Index (ISI Web of Science)
- Conference Proceedings Citation Index – Science (ISI Web of Science)
- Cochrane Library (Wiley Interscience):
  - Cochrane Database of Systematic Reviews
  - Cochrane Central Register of Controlled Trials
  - Database of Abstracts of Reviews of Effects (DARE)
  - Health Technology Assessment Database (HTA)
- ClinicalTrials.gov (www.clinicaltrials.gov)
- International Clinical Trials Registry Platform (http://www.who.int/ictrp/en/)
- metaRegister of Controlled Trials (http://www.controlled-trials.com/mrct/)
- US Food and Drug Administration (www.fda.gov/)
- European Medicines Agency (www.ema.europa.eu/)
- National Institute for Health and Care Excellence (http://www.nice.org.uk/)
- American Society for Clinical Oncology (ASCO) annual meeting (www.asco.org)
- European Society for Medical Oncology (ESMO) annual meeting (www.esmo.org/)
- International Society for Pharmacoeconomics and Outcomes Research (www.ispor.org)
- European CanCer Organisation (ECCO) and European Breast Cancer Conference (EBCC) annual meeting (www.ecco-org.eu/)
- San Antonio Breast Cancer Symposium (SABC) (www.sabcs.org/)

For all databases, search terms included the term 'everolimus'. For MEDLINE and MEDLINE In-Process, EMBASE and Science Citation Index, searches were also limited to second line or recurrent advanced breast cancer or metastatic breast cancer. No language, study or date restrictions were employed, nor were any search filters used.

The search strategies employed appear to be comprehensive. The ERG also conducted its own searches of MEDLINE and MEDLINE In-Process (Ovid SP), EMBASE (Ovid SP), ASCO and SABCS on 5 December 2012 and did not identify any additional potentially relevant

studies.

Mixed Treatment Comparison

A series of searches was undertaken by the manufacturer on 22 March 2012 to identify systematic reviews and trials which could be used to provide indirect comparisons. The first searches were undertaken in the following databases:

- MEDLINE and MEDLINE In-Process (OvidSP)
- EMBASE (OvidSP)
- The Cochrane Library (Wiley Interscience)
- ClinicalTrials.gov (http://clinicaltrials.gov/)
- ICTRP (www.who.int/ictrp/)

A second series of searches were undertaken on 26 March 2012 in the Cochrane Library databases via the Wiley Interscience interface, specifically the Cochrane Database of Systematic Reviews (CDSR) and the DARE and HTA database. Searches were also undertaken on the National Horizon Scanning Centre website and the NICE website.

For all databases, search terms were limited to identify breast cancer studies and, where databases allowed, attempts were made to limit the searches to identify randomised controlled trials (RCTs) and systematic reviews/meta-analyses. No language, study or drug restrictions were employed. Date restrictions were only employed for searches of the DARE and HTA databases (to 2010-2012 publications).

The search strategies employed appear to be appropriate. The ERG also conducted its own searches of the Cochrane Library (Wiley Interscience), MEDLINE and MEDLINE In-Process (Ovid SP) on 16 November 2012 and did not identify any additional potentially relevant studies.

Naïve Chained Indirect Analysis

In order to conduct the 'naïve chained indirect analysis', a 'rapid search' of the Cochrane Library (Cochrane Database of Systematic Reviews, DARE and HTA databases) was conducted to identify systematic reviews and health technology assessments of chemotherapy and advanced or metastatic breast cancer. The precise detail of the search strategy is not provided in the manufacturer's submission (MS) but it is stated that it 'was designed to be sensitive in order to identify all systematic reviews and health technology assessments about advanced or metastatic breast cancer' and, for DARE and HTA, limited to reviews published from 2010 to 2012.

It is not possible to assess the appropriateness of the search strategy employed from the level of detail provided. However the ERG conducted its own searches of the Cochrane Library (Wiley Interscience), MEDLINE and MEDLINE In-Process (Ovid SP) on 16 November 2012 and did not identify any additional potentially relevant reviews.

Inclusion Criteria

Systematic Review

The MS presented the inclusion and exclusion criteria for its systematic review. These are reproduced in the Table below.

	Clinical Effectiveness
Inclusion Criteria	*Population*: postmenopausal women with hormone-receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer whose disease had recurred or progressed following endocrine therapy, including treatment with non-steroidal aromatase inhibitors *Intervention*: everolimus in combination with exemestane, fulvestrant or tamoxifen *Comparator*: exemestane, fulvestrant or tamoxifen *Outcomes*: clinical benefit rate (CBR), response rate (complete, partial, stable disease), overall survival (OS), progression-free survival (PFS) or time to progression (TTP), adverse events (AEs) and discontinuations due to AEs, health-related quality of life (HRQoL), time to treatment discontinuation *Study design*: randomised controlled trials (RCTs) of any duration and crossover RCTs if data were presented at crossover; non-randomised comparative and uncontrolled studies reporting AEs were also eligible for inclusion

	Clinical Effectiveness *Language*: there was no language restriction applied to the search; studies with English abstracts, but whose full reports were in languages other than English were not extracted but were listed for information only *Publication status*: published, unpublished and grey literature was eligible; studies published as abstracts or conference presentations were included if an associated published full paper could not be found and adequate data were presented
Exclusion Criteria	None specified

Mixed Treatment Comparison

The search results were assessed for relevance to drug interventions for women with HR-positive advanced or metastatic breast cancer. To achieve a network, the following eligibility criteria were relaxed for record selection from the results of the second searches:

- HER2-negative status: trials with mixed populations and where the HER2 status was not reported were considered eligible.
- Treatment lines other than second line were considered eligible.

Naïve Chained Indirect Analysis

Explicit inclusion and exclusion criteria for the 'naïve chained indirect analysis' were not presented in the MS. However, it is stated that having identified potentially relevant reviews, these 'were then sifted to remove those reviews that were not about drug interventions for advanced or metastatic breast cancer: surgery, radiotherapy, non-drug treatments, screening, prevention, etc.' Without greater detail, it is not possible to comment on the appropriateness of the inclusion and exclusion criteria employed. However, the ERG does not believe that any relevant reviews were excluded.

Cost-effectiveness

Objective of the Manufacturer's Cost-effectiveness Literature Review

The manufacturer carried out a search to identify studies reporting the cost-effectiveness of everolimus in postmenopausal women with HR-positive, HER2-negative, advanced (locally advanced or metastatic) breast cancer who had already received endocrine therapy.

The databases searched included: MEDLINE, MEDLINE In-Process, EMBASE, EconLit and the National Health Service Economic Evaluation Database (NHS EED). All searches were carried out on 8 and 9 March 2012. The search strategy used did not include an economic search filter because scoping searches had indicated that the amount of literature for everolimus was very small. The search strategies comprised the drug name in combination with search terms for advanced or metastatic breast cancer. No date or language limits were applied. Full details of the search strategies, as well as the databases and resources searched, are provided in the MS.

Conclusions of the Cost-effectiveness Literature Review

The manufacturer's search to identify studies reporting the cost-effectiveness of everolimus in postmenopausal women with HR-positive, HER2-negative, advanced (locally advanced or metastatic) breast cancer who had already received endocrine therapy did not identify any relevant cost-effectiveness studies. The ERG is satisfied with the manufacturer's search strategy and is reasonably confident that the manufacturer did not miss any relevant published articles.

Number of Source Documents

Clinical Effectiveness

- One randomised controlled trial (RCT) was identified for inclusion in the systematic review.
- One other open-label phase II trial provided supporting evidence.
- Three more studies were included for mixed treatment comparison.

Cost-effectiveness

- No relevant cost-effectiveness studies were identified.
- The manufacturer submitted an economic evaluation.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the Liverpool Reviews and Implementation Group (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Data Extraction

Systematic Review

The manufacturer described the data it planned to extract for its systematic review in the manufacturer's submission (MS). These data appear to be appropriate. It is not clear whether the data extracted from any study was cross-checked. For the main trial (BOLERO-2) that provided the majority of the evidence in the MS, the ERG has cross-checked much of the data extracted with the published paper and the European Medicines Agency Committee for Medical Products for Human Use European Public Assessment Report (EMA CHMP EPAR). It is difficult to determine if any relevant data has not been extracted without access to the Clinical Study Report but, based on the information provided in the protocol and statistical analysis plan, it appears that the majority of the analyses that were planned were reported in the MS. However, these were not always reported for the most recent data cut off (18 months). In its clarification letter to the manufacturer, the ERG therefore requested the following data at 18 months:

- Duration of exposure to study treatment
- Time to response
- Duration of response
- Treatment received after discontinuation

All of these data were provided by the manufacturer, although all were deemed to be commercial in confidence (CIC) and therefore, wherever possible, the ERG has attempted to report only data that are not CIC.

Mixed Treatment Comparison

The manufacturer described the data it planned to extract for its mixed treatment comparison in the MS. These data appear to be appropriate. However, it is not clear whether the data extracted from any study was cross-checked. The ERG has cross-checked the data extracted with the published papers (and where applicable, previous documentation for NICE single technology appraisals [STAs] and Conference slides) for each study and in some instances, identified some minor errors; where appropriate, these have been corrected in the tables throughout the ERG report.

Naïve Chained Indirect Analysis

The manufacturer does not describe its data extraction strategy for the 'naïve chained indirect analysis' in the MS. However, it would appear that, in addition to the data from the TAMRAD study extracted for the manufacturer's systematic review, only the value of the hazard ratio for the comparison between chemotherapy and endocrine therapy from another systematic review by Wilcken et al. was extracted. It is not clear whether the data extracted was cross-checked. However, the ERG has cross-checked the extracted data and has not identified any errors.

Quality Assessment

Systematic Review

The manufacturer conducted an assessment of risk of bias for studies included in its systematic review. It was conducted by using a checklist recommended by the Cochrane Collaboration and presented in the MS. The ERG conducted its own assessment of risk of bias for these studies using the same checklist and largely reached conclusions that were similar to those of the manufacturer.

Mixed Treatment Comparison

The manufacturer conducted an assessment of risk of bias for all included studies in the mixed treatment analysis. It was conducted by using a checklist recommended by the Cochrane Collaboration and presented in the MS. The ERG conducted its own assessment of risk of bias for these studies using the same checklist and reached conclusions which were similar to those of the manufacturer.

Naïve Chained Indirect Analysis

No assessment of risk of bias was specifically presented for the 'naïve chained indirect analysis' although the primary studies included did not differ from those in the systematic review or mixed treatment comparison and so had already been assessed for risk of bias. However, it is not clear if the quality of the identified systematic review was assessed.

Refer to the appendices in the ERG report for information on assessment of risk of bias for studies included in the MS.

Evidence Synthesis

Systematic Review

Because the studies identified for inclusion into the systematic review had different interventions and comparators, the manufacturer appropriately synthesised the data by reporting on each trial individually and did not attempt a meta-analysis.

Mixed Treatment Comparison

The manufacturer performed mixed treatment comparison analyses on two outcomes; progression-free survival (PFS or time to progression [TTP]) and overall survival (OS). Log hazard ratios were used to inform the analyses, and the results were presented as hazard ratios for fulvestrant versus exemestane and fulvestrant versus everolimus in combination with exemestane. The ERG believes this was the most appropriate way to synthesise the data.

Naïve Chained Indirect Analysis

No data synthesis of the 'naïve chained indirect analysis' was undertaken in the clinical section of the MS. The findings from this analysis were used to inform the cost-effectiveness analysis.

Refer to Section 4 of the ERG report for more information.

<u>Cost-effectiveness</u>

Model Structure

A schematic of the model structure is shown in Figure 5 of the ERG report.

Three health states are used to model disease progression. All patients enter the model in the Stable (PFS) health state and in each month can either progress to a 'worse' health state (i.e., from Stable to Progressed or Dead, or from Progressed to Dead) or remain in the same health state. Subsequent lines of therapy are not considered in the model.

The model has been developed in MS Excel and has a one month cycle length. It includes a half-cycle correction and the base case time horizon is 10 years. A discount rate of 3.5% has been used for both costs and outcomes. The perspective is that of the National Health Service (NHS).

Sensitivity Analyses

The manufacturer undertook a wide range of sensitivity analyses. Results of their deterministic sensitivity analyses are not included in the MS. The figures in Table 33 of the ERG report have, therefore, been generated from the model by the ERG.

Results from the scenario analyses carried out by the manufacturer are presented in Table 34 of the ERG report. The manufacturer also undertook probabilistic sensitivity analysis (PSA) to derive the mean incremental cost effectiveness ratio (ICER) per quality-adjusted life year (QALY) of

everolimus plus exemestane compared with exemestane alone. The distributions used in the PSA are summarised in Table 35 of the ERG report.

Model Validation and Face Validity Check

The manufacturer reports that the model was subjected to a rigorous 'pressure test' to identify potential errors. Internal validation was undertaken by varying an extensive list of inputs and comparing the impact against expected results. In addition, detailed testing of the model's formulae and functionality was undertaken. A summary of the tests conducted is provided in the MS.

Refer to Section 5 of the ERG report for additional information on cost-effectiveness.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Summary of Appraisal Committee's Key Conclusions on Cost-effectiveness

Availability and Nature of Evidence

The Committee considered the manufacturer's economic model and the Evidence Review Group (ERG)'s critique of the manufacturer's comparison of everolimus plus exemestane and exemestane alone.

The Committee noted that the incremental cost-effectiveness ratios (ICERs) were most sensitive to the modelling of overall survival and progression-free survival assessment method.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

The Committee agreed that the most plausible ICER should be based on an analysis using the following assumptions: using exponential functions to estimate progression-free survival and the non-parallel model of overall survival; omitting the adjustment factor from Beauchemin et al. (2012); using locally assessed trial data; including adverse reactions; using rates of adverse reactions as documented in the European Public Assessment Report; recalculating time on treatment; including costs of monitoring disease that has not progressed; correcting discounting and utility values for stable disease; using the utility value for 'progressed disease' from Lloyd et al. (2006); and omitting extra mortality from non-cancer causes.

Incorporation of Health-Related Quality-of-Life Benefits and Utility Values

The Committee concluded that neither valuation of utility for the 'progressed disease' health state was without uncertainty, but that the data from Lloyd et al. (2006) were more appropriate than the data from Launois et al. (1997).

Have Any Potential Significant and Substantial Health-Related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

Although the Committee acknowledged that the mechanism of action of everolimus may offer a step change in treatment by restoring sensitivity of the tumour to endocrine therapy, it concluded that the manufacturer had not submitted convincing evidence that everolimus (plus exemestane) provides health-related quality-of-life benefits exceeding that calculated in the quality-adjusted life year (QALY).

Are There Specific Groups of People for Whom the Technology Is Particularly Cost-effective?

The Committee concluded that the available evidence did not allow it to make any recommendations specific to subgroups of patients.

What Are the Key Drivers of Cost-effectiveness?

Using local or central assessment for progression-free survival in the modelling: The Committee concluded that it was more appropriate to use effectiveness data derived from local assessment in the modelling than from central assessment because local assessment represented the primary end point of the trial, reflected clinical practice and minimised the potential for bias from informative censoring.

Choice of survival modelling: The Committee agreed that the manufacturer's estimated 10.5 months' survival benefit with the Weibull analysis was likely to be optimistic, and that the estimated 1.4 months' survival benefit with the ERG's exploratory parallel exponential model was likely to be pessimistic. It acknowledged that the overall survival benefit of everolimus plus exemestane is uncertain but probably lies between these estimates. The Committee noted that it is also similar to the overall survival benefit from the ERG's non parallel exponential model (4.6 months), which reflects the longer progression-free survival with everolimus plus exemestane than with exemestane alone.

Most Likely Cost-Effectiveness Estimate (Given as an ICER)

The Committee concluded that the ERG's estimate of the ICER (including the patient access scheme for everolimus) of £68,000 per QALY gained for everolimus plus exemestane compared with exemestane alone was more plausible than the manufacturer's base-case estimate.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated for each recommendation.

The Appraisal Committee considered clinical and cost-effectiveness evidence submitted by the manufacturer and a review of this submission by the Evidence Review Group. For clinical effectiveness, one randomised controlled trial was the main source of evidence. For cost-effectiveness, the manufacturer's model was considered.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate recommendation for the use of everolimus in combination with exemestane for treating advanced human epidermal growth factor receptor 2 (HER2)-negative hormone-receptor-positive breast cancer after endocrine therapy

Potential Harms

The summary of product characteristics lists the following as the most frequently reported grade 3 or 4 adverse reactions: anaemia, fatigue, diarrhoea, infections, stomatitis, hyperglycaemia, thrombocytopenia, lymphopenia, neutropenia, hypophosphataemia, hypercholesterolaemia, diabetes mellitus and pneumonitis.

For full details of adverse reactions and contraindications, see the summary of product characteristics.

Contraindications

Contraindications

Everolimus is contraindicated in people who are hypersensitive to the active substance, to derivatives of rapamycin, or to any of the excipients used to make everolimus.

For full details of adverse reactions and contraindications, see the summary of product characteristics.

Qualifying Statements

Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

The National Institute for Health and Care Excellence (NICE) has developed a costing statement explaining the resource impact of this guidance. This tool is available from the NICE Web site (see also the Availability of Companion Documents" field).

Implementation Tools

Foreign Language Translations

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Aug. 62 p. (Technology appraisal guidance; no. 295).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Aug

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Appraisal Committee

Composition of Group That Authored the Guideline

Committee Members: Dr Amanda Adler (*Chair*), Consultant Physician, Addenbrooke's Hospital; Professor Ken Stein (*Vice Chair*), Professor of Public Health, Peninsula Technology Assessment Group (PenTAG), University of Exeter; Dr Ray Armstrong, Consultant Rheumatologist, Southampton General Hospital; Dr Jeff Aronson, Reader in Clinical Pharmacology, University Department of Primary Health Care, University of Oxford; Professor John Cairns, Professor of Health Economics Public Health and Policy, London School of Hygiene and Tropical Medicine; David Chandler, Lay Member; Mark Chapman, Health Economics and Market Access Manager, Medtronic UK; Professor Fergus Gleeson, Consultant Radiologist, Churchill Hospital, Oxford; Robert Hinchliffe, HEFCE Clinical Senior Lecturer in Vascular Surgery and Honorary Consultant Vascular Surgeon, St George's Vascular Institute; Professor Daniel Hochhauser, Consultant in Medical Oncology, UCL Cancer Institute; Dr Neil Iosson, General Practitioner; Anne Joshua, Associate Director of Pharmacy, NHS Direct; Dr Rebecca Kearney, Clinical Lecturer, University of Warwick; Terence Lewis, Lay Member; Professor Ruairidh Milne, Director of Strategy and Development and Director for Public Health Research at the National Institute for Health Research (NIHR) Evaluation, Trials and Studies Coordinating Centre at the University of Southampton; Dr Elizabeth Murray, Reader in Primary Care, University College London; Dr Peter Norrie, Principal Lecturer in Nursing, DeMontfort University; Professor Stephen Palmer, Professor of Health Economics, Centre for Health Economics, University of York; Dr Sanjeev Patel, Consultant Physician & Senior Lecturer in Rheumatology, St Helier University Hospital; Dr John Pounsford, Consultant Physician, Frenchay Hospital, Bristol; Dr Danielle Preedy, Lay Member; Cliff Snelling, Lay Member; Marta Soares, Research Fellow, Centre for Health Economics, University of York; Professor Andrew Stevens, Professor of Public Health, Department of Public Health and Epidemiology, University of Birmingham; Dr Nerys Woolacott, Senior Research Fellow, Centre for Health Economics, University of York; Dr Nicky Welton, Senior Lecturer in Biostatistics/Health Technology Assessment, University of Bristol

Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

Availability of Companion Documents

The following are available:

- Fleeman N, Bagust A, Beale S, Blundell M, Dwan K, Pilkington G, Proudlove C, Dundar Y, Vecchio F, Thorp N. Everolimus in combination with an aromatase inhibitor for the treatment of breast cancer after prior endocrine therapy: a single technology appraisal. Liverpool (UK): LRiG, The University of Liverpool; 2013. 101 p. Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Care Excellence (NICE) Web site .
- Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy. Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Aug. 3 p. (Technology appraisal guidance; no. 295). Electronic copies: Available in PDF from the NICE Web site .

Patient Resources

The following is available:

- Everolimus given with exemestane for advanced breast cancer. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Aug. 6 p. (Technology appraisal guidance; no. 295). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Care Excellence (NICE) Web site . Also available in Welsh from the NICE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on November 20, 2013.

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